

GOLYTELY- polyethylene glycol 3350, sodium sulfate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride powder, for solution
Braintree Laboratories, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GOLYTELY safely and effectively. See full prescribing information for GOLYTELY.

GOLYTELY (polyethylene glycol 3350 and electrolytes for oral solution)

Initial U.S. Approval: 1984

-----**RECENT MAJOR CHANGES**-----

Warnings and Precautions, Aspiration: (5.7)

05/2021

-----**INDICATIONS AND USAGE**-----

GoLYTELY is a combination of PEG 3350, an osmotic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy and barium enema X-ray examination in adults (1)

-----**DOSAGE AND ADMINISTRATION**-----

Preparation and Administration (2.1):

- Correct fluid and electrolyte abnormalities before treatment with GoLYTELY.
- Reconstitute GoLYTELY with water prior to ingestion.
- Do not take oral medications within 1 hour before the start or during administration of GoLYTELY. (2.1)
- Do not take other laxatives while taking GoLYTELY.
- Consume only clear liquids; avoid red and purple liquids.
- Consume water or other clear liquids up until 2 hours before the time of the colonoscopy.
- Do not consume solid food within 2 hours before starting GoLYTELY.

Adult Dosing Regimen (2.2):

- On day prior to colonoscopy, instruct patients to consume a light breakfast at least 2 hours before starting GoLYTELY.
- Begin the recommended dosage regimen for GoLYTELY early in the evening on the day before colonoscopy
- Drink reconstituted solution at a rate of 8 ounces every 10 minutes, until 4 liters are consumed, or rectal effluent is clear.
- For complete information on dosing, preparation and administration, see the full prescribing information. (2.1, 2.2)

-----**DOSAGE FORMS AND STRENGTHS**-----

For Oral Solution: 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride per 4 liters. (3)

-----**CONTRAINDICATIONS**-----

- Gastrointestinal (GI) obstruction (4, 5.6)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Ileus (4)
- Hypersensitivity to components of GoLYTELY (4, 5.8)

-----**WARNINGS AND PRECAUTIONS**-----

- Risk of fluid and electrolyte abnormalities: Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use. (5.1, 5.2, 7.1)
- Cardiac arrhythmias: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias. (5.2)

- Seizures: Use caution in patients with a history of seizures and patients at increased risk of seizure, including medications that lower the seizure threshold. (5.3, 7.1)
- Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider testing. (5.4, 7.1, 8.6)
- Mucosal ulcerations: Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. (5.5, 7.3)
- Patients at risk for aspiration: Observe during administration. (5.7)
- Hypersensitivity reactions including anaphylaxis: Inform patients to seek immediate medical care if symptoms occur. (5.8)

-----ADVERSE REACTIONS-----

Most common adverse reactions are: nausea, abdominal fullness, bloating, abdominal cramps, vomiting and anal irritation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Braintree Laboratories, Inc. at 1-800-874-6756 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

Some drugs increase risks due to fluid and electrolyte changes (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 5/2021

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

GoLYTELY is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation and Administration Instructions

- Correct fluid and electrolyte abnormalities before treatment with GoLYTELY [see *Warnings and Precautions (5.1)*].
- Reconstitute GoLYTELY with water prior to ingestion, do not take undissolved GoLYTELY [see *Dosage and Administration (2.2)*]. Do not reconstitute with other liquids and/or add starch-based thickeners to the mixing container [see *Warnings and Precautions (5.7)*].
- Do not take oral medications within 1 hour before the start of or during administration of GoLYTELY [see *Drug Interactions (7.2)*].
- Do not take other laxatives while taking GoLYTELY [see *Drug Interactions (7.3)*].
- Consume only clear liquids, avoid red and purple liquids.
- Patients may consume water or other clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
- The solution is more palatable if chilled prior to administration.
- Do not consume solid food within 2 hours before starting GoLYTELY. For the best results, do not consume solid food for 3 to 4 hours before drinking the solution.
- If severe bloating, distention or abdominal pain occurs, slow or temporarily discontinue GoLYTELY until the symptoms abate.

2.2 Dosage Regimen

Instruct adult patients that on the day before the colonoscopy procedure, they may consume a light breakfast at least 2 hours before starting GoLYTELY. Begin the recommended dosage regimen for GoLYTELY early in the evening on the day before colonoscopy.

Instruct patients to take GoLYTELY in conjunction with clear liquids as follows:

4 Liter Jug

- Fill the supplied container containing the GoLYTELY powder with lukewarm drinking water to the 4-liter fill line
- Do not add any other ingredients, flavors, etc.
- After capping the container, shake vigorously several times to ensure that the ingredients are dissolved.
- Drink at a rate of 8 ounces every 10 minutes until the entire contents are consumed or the rectal effluent is clear. A loose watery bowel movement should result in approximately one hour.
- After reconstitution, keep solution refrigerated 2° to 8°C (36° to 46°F). Do not freeze. Use within 48 hours, discard unused portion.

Administration via a Nasogastric Tube

For patients with a nasogastric tube, administer the reconstituted GoLYTELY solution at a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour).

3 DOSAGE FORMS AND STRENGTHS

For Oral Solution: 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride as a white powder. When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG-3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride.

4 CONTRAINDICATIONS

GoLYTELY is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction [*see Warnings and Precautions (5.6)*]
- Bowel perforation [*see Warnings and Precautions (5.6)*]
- Toxic colitis or toxic megacolon
- Gastric retention
- Ileus
- Hypersensitivity to any component of GoLYTELY [*see Warnings and Precautions (5.8)*]

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

Advise patients to hydrate adequately before, during, and after the use of GoLYTELY. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops significant vomiting or signs of dehydration including signs of orthostatic hypotension after taking GoLYTELY, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Correct fluid and electrolyte abnormalities before treatment with GoLYTELY.

In addition, use caution when prescribing GoLYTELY for patients who have conditions, or

who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment [*see Drug Interactions (7.1)*].

5.2 Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing GoLYTELY for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Consider pre-dose and post-colonoscopy ECGs in patients at increased risk of serious cardiac arrhythmias.

5.3 Seizures

There have been reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing GoLYTELY for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia [*see Drug Interactions (7.1)*].

5.4 Renal Impairment

Use caution when prescribing GoLYTELY for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs) [*see Drug Interactions (7.1)*]. Advise these patients of the importance of adequate hydration and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients [*see Use in Specific Populations (8.6)*].

5.5 Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and GoLYTELY may increase this risk [*see Drug Interactions (7.3)*]. Consider the potential for mucosal ulcerations resulting from the bowel preparation when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

5.6 Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering GoLYTELY [*see Contraindications (4)*]. Use with caution in patients with severe active ulcerative colitis.

5.7 Aspiration

Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Observe these patients during administration of GoLYTELY, especially if it is administered via nasogastric tube. Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Observe these patients during administration of GoLYTELY, especially if it is administered via nasogastric tube.

Do not combine GoLYTELY with starch-based thickeners [see *Dosage and Administration (2.1)*]. Polyethylene glycol (PEG), a component of GoLYTELY, when mixed with starch-thickened liquids reduces the viscosity of the starch-thickened liquid. When a PEG-based product used for another indication was mixed in starch-based pre-thickened liquids used in patients with dysphagia, thinning of the liquid occurred and cases of choking and potential aspiration were reported.

5.8 Hypersensitivity Reactions

GoLYTELY contains PEG and may cause serious hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, and pruritus [see *Adverse Reactions (6)*]. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Renal impairment [see *Warnings and Precautions (5.4)*]
- Colonic mucosal ulcerations and ischemic colitis [see *Warnings and Precautions (5.5)*]
- Patients with significant gastrointestinal disease [see *Warnings and Precautions (5.6)*]
- Aspiration [see *Warnings and Precautions (5.7)*]

The following adverse reactions associated with the use of GoLYTELY were identified in clinical trials or postmarketing reports. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or establish a causal relationship to drug exposure.

- Cardiovascular: arrhythmia, atrial fibrillation, peripheral edema, asystole, and acute pulmonary edema after aspiration [see *Warnings and Precautions (5.2)*].
- Nervous system: tremor, seizure [see *Warnings and Precautions (5.3)*]
- Hypersensitivity: Urticaria/rash, pruritus, dermatitis, rhinorrhea, dyspnea, chest and throat tightness, fever, angioedema, anaphylaxis and anaphylactic shock [see *Contraindications (4), Warnings and Precautions (5.8)*]
- Gastrointestinal: Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients). Other less common adverse reactions include: abdominal cramps, vomiting, “butterfly-like” infiltrates on chest X-

ray after vomiting and aspirating PEG, anal irritation, and upper GI bleeding from Mallory-Weiss Tear, esophageal perforation [usually with gastroesophageal reflux disease (GERD)].

7 DRUG INTERACTIONS

7.1 Drugs that May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing GoLYTELY for patients with conditions and/or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of renal impairment, seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities [*see Warnings and Precautions (5.1, 5.2, 5.3, 5.4)*]. Consider additional patient evaluations as appropriate.

7.2 Potential for Reduced Drug Absorption

GoLYTELY can reduce the absorption of other administered drugs. Administer oral medications within one hour before the start of administration of GoLYTELY [*see Dosage and Administration (2.1)*].

7.3 Stimulant Laxatives

Concurrent use of stimulant laxatives and GoLYTELY may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking GoLYTELY [*see Warnings and Precautions (5.5)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies have not been conducted with GoLYTELY. It is also not known whether GoLYTELY can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GoLYTELY should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GoLYTELY is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of GoLYTELY in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of GoLYTELY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

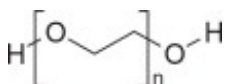
8.6 Renal Impairment

Use GoLYTELY with caution in patients with renal impairment or patients taking concomitant medications that may affect renal function [see *Drug Interactions (7.1)*]. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after use of GoLYTELY and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients [see *Warnings and Precautions (5.4)*].

11 DESCRIPTION

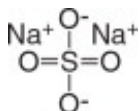
GoLYTELY is a combination of polyethylene glycol 3350, an osmotic laxative, and electrolytes (sodium sulfate, sodium chloride, sodium bicarbonate and potassium chloride) for oral solution supplied in a 4-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride, and 2.97 g potassium chloride as a white powder.

Polyethylene Glycol 3350, USP



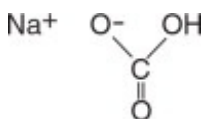
Sodium Sulfate, USP

The chemical name is Na₂SO₄. The average Molecular Weight is 142.04. The structural formula is:



Sodium Bicarbonate, USP

The chemical name is NaHCO₃. The average Molecular Weight is 84.01. The structural formula is:



Sodium Chloride, USP

The chemical name is NaCl. The average Molecular Weight: 58.44. The structural formula is:

Na⁺ Cl⁻

Potassium Chloride, USP

The chemical name is KCl. The average Molecular Weight: 74.55. The structural formula is:

K-Cl

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350 which causes water to be retained in the colon and produces a watery stool.

12.2 Pharmacodynamics

GoLYTELY induces as diarrhea which rapidly cleanses the bowel, usually within four hours.

12.3 Pharmacokinetics

The pharmacokinetics of PEG3350 following administration of GoLYTELY were not assessed. Available pharmacokinetic information for oral PEG3350 suggests that it is poorly absorbed.

16 HOW SUPPLIED/STORAGE AND HANDLING

GoLYTELY (polyethylene glycol 3350 and electrolytes for oral solution) is supplied in a 4-liter disposable jug containing 236 g polyethylene glycol 3350, 22.74 g sodium sulfate (anhydrous), 6.74 g sodium bicarbonate, 5.86 g sodium chloride and 2.97 g potassium chloride as a white powder.

- When reconstituted with water to a volume of 4 liters, the solution contains 59 g/L PEG-3350, 5.69 g/L sodium sulfate, 1.69 g/L sodium bicarbonate, 1.47 g/L sodium chloride and 0.743 g/L potassium chloride.

GoLYTELY 4 Liter Disposable Jug NDC 52268-100-01

Storage

Store in sealed container at 15° to 30°C (59° to 86°F).

Store reconstituted solution of GoLYTELY at 2° to 8°C (36° to 46°F). Do not freeze [*see Dosage and Administration (2.1)*].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-Approved Patient Labeling (Medication Guide and Instructions for Use).

Instruct Patients:

- To reconstitute GoLYTELY with water prior to ingestion.
- Not to take other laxatives while they are taking GoLYTELY.
- Not to take oral medications within 1 hour before the start or during the administration of GoLYTELY.

- To take only clear liquids but avoid red and purple liquids.
- To consume water or other clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.
- To follow the directions in the *Instructions for Use* on how to prepare and administer the product.
- If they experience severe bloating, distention or abdominal pain, to slow or temporarily discontinue drinking the solution and to contact their healthcare provider.
- To contact their healthcare provider if they develop signs and symptoms of dehydration or if they experience altered consciousness or seizures. [see *Warnings and Precautions* (5.1, 5.2, 5.3, 5.4)] .
- To discontinue administration of the solution and contact their healthcare provider if they develop symptoms of a hypersensitivity reaction [see *Warnings and Precautions* (5.8)] .

Manufactured by Braintree Laboratories, Inc. 270 Centre Street Holbrook, MA 02343

Marketed by Braintree, a Part of Sebelo Pharmaceuticals®. 60 Columbian Street West Braintree, MA 02185

Medication Guide

GoLYTELY® (Go-lite-ly)
(PEG-3350 and Electrolytes)
for oral solution

Read this Medication Guide before you start taking GoLYTELY. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about GoLYTELY? GoLYTELY and other osmotic bowel preparations can cause serious side effects, including:

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

These changes can cause:

- **abnormal heartbeats (arrhythmias) that can cause death.**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems.**

Your chance of having fluid loss and changes in body salts with GoLYTELY is higher if you:

- have heart problems.
- have kidney problems.
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS).

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid

(dehydration) while taking GoLYTELY:

- vomiting that prevents you from keeping down the solution.

- dizziness.
- urinating less often than normal.
- headache.

See Section “What are the possible side effects of GoLYTELY” for more information about side effects.

What is GoLYTELY?

GoLYTELY is a prescription medicine used by adults to clean the colon before a colonoscopy or barium enema X-ray examination. GoLYTELY cleans your colon by causing you to have diarrhea (loose stools). Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy. It is not known if GoLYTELY is safe and effective in children.

Who should not take GoLYTELY?

Do not take GoLYTELY if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction).
- an opening in the wall of your stomach or intestine (bowel perforation).
- a very dilated intestine (toxic megacolon).
- problems with food and fluid emptying from your stomach (gastric retention).
- a problem with food moving too slowly through your intestines (ileus).
- an allergy to any of the ingredients in GoLYTELY. See the end of this Medication Guide for a complete list of ingredients in GoLYTELY.

What should I tell my healthcare provider before taking GoLYTELY?

Before you take GoLYTELY, tell your healthcare provider if you:

- have heart problems.
- have stomach or bowel problems.
- have ulcerative colitis.
- have problems with swallowing or gastric reflux.
- have a history of seizures.
- are withdrawing from drinking alcohol.
- have a low blood salt (sodium) level.
- have kidney problems.
- have any other medical conditions.
- are pregnant. It is not known if GoLYTELY will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if GoLYTELY passes into your breast milk. You and your healthcare provider should decide if you will take GoLYTELY while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GoLYTELY may affect how other medicines work. Do not take medicines by mouth within 1 hour of starting GoLYTELY or after you start taking GoLYTELY. **Especially tell your healthcare provider if you take:**

- medicines for blood pressure or heart problems.
- medicines for kidney problems.
- medicines for seizures.
- water pills (diuretics).

- non-steroidal anti-inflammatory medicines (NSAID) pain medicines.
- laxatives.
- starch-based thickeners. For patients who have trouble swallowing, do not mix GoLYTELY with starch-based thickeners.

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take GoLYTELY?

You must read, understand, and follow these instructions to take GoLYTELY the right way.

- Take GoLYTELY exactly as your healthcare provider tells you to take it
- See the “Instructions for Use” on the bottle label for instructions on how to mix, take or give GoLYTELY.
- **Do not take undissolved GoLYTELY powder that has not been mixed with water (diluted). It may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Do not take other laxatives while taking GoLYTELY.
- Drink reconstituted solution at a rate of 8 ounces (240 ml) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- **Do not eat or drink anything colored red or purple.**
- **Do not eat solid foods at least 2 hours before taking GoLYTELY.** You may eat a light breakfast 2 hours before taking GoLYTELY. For best results, do not consume solid food for 3 to 4 hours before drinking GoLYTELY.
- Drink only water and clear liquids:
 - the day before your colonoscopy
 - while taking GoLYTELY
 - after taking GoLYTELY until 2 hours before your colonoscopy.
- Drink clear liquids before, during, and after you take GoLYTELY to avoid fluid loss (dehydrated). Examples of clear liquids are:
 - water • clear broth
 - clear fruit juices without pulp including apple, white grape, • clear soda or white cranberry
 - strained limeade or lemonade • gelatin (without added fruit or topping)
 - coffee or tea (Do not use any dairy or non-dairy creamer) • popsicles without pieces of fruit or fruit pulp
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, slow or temporarily stop (discontinue) drinking the solution and contact your healthcare provider.
- The first bowel movement should occur approximately one hour after you start

drinking the solution.

- Continue drinking until the watery stool is clear and free of solid matter.

What are the possible side effects of GoLYTELY?

GoLYTELY can cause serious side effects, including:

- **See Section “What is the most important information I should know about GoLYTELY?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests before and after you take GoLYTELY to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting • stomach (abdominal) cramping
 - nausea ♦ • headache
 - bloating • urinate less than usual
 - dizziness • trouble drinking clear liquid
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of GoLYTELY include:

- nausea • stomach (abdominal) cramps • anal irritation
- stomach (abdominal) fullness • vomiting • esophageal bleeding
- bloating • chest x-ray that shows water in

the lungs (infiltrate) after

vomiting or inhaling food or liquid

(aspirate).

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of GoLYTELY. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GoLYTELY?

- Store GoLYTELY in a sealed container at room temperature, between 59°F to 86°F (15°C to 30°C).
- Store mixed (reconstituted) solution of GoLYTELY at 36° to 46°F (2°C to 8°C). Do not freeze.
- Use mixed (reconstituted) solution of GoLYTELY within 48 hours.
- After 48 hours, throw away (discard) any mixed (reconstituted) solution of GoLYTELY

that is not used.

Keep GoLYTELY and all medicines out of the reach of children.

General information about the safe and effective use of GoLYTELY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GoLYTELY for a condition for which it was not prescribed. Do not give GoLYTELY to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes important information about GoLYTELY. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

What are the ingredients in GoLYTELY?

GoLYTELY comes in a 4-liter jug with GoLYTELY powder.

Active ingredients:

Powder for solution: polyethylene glycol 3350, sodium sulfate (anhydrous), sodium bicarbonate, sodium chloride, and potassium chloride.

Manufactured by Braintree Laboratories, Inc.

270 Centre Street

Holbrook, MA 02343

Marketed by Braintree, a Part of Sebelo Pharmaceuticals®

60 Columbian Street West

Braintree, MA 02185

For more information go to www.braintreelabs.com or call 1-800-874-6756.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 05/2021

Principal Display Panel

FILL TO THE TOP OF THE LINE ON BOTTLE

NDC 52268-100-01

TO PHARMACIST AND PATIENT: Mixing information is on base label.

Package insert may be removed before dispensing.

Dispense the enclosed Medication Guide to each patient.

GoLYTELY®

PEG-3350 and Electrolytes for Oral Solution

When reconstituted with water to a volume of 4 liters, this solution contains PEG-3350 59 g/L, sodium sulfate 5.69 g/L, sodium bicarbonate 1.69 g/L, sodium chloride 1.47 g/L, and potassium chloride 0.743 g/L.

Each disposable jug contains, in powdered form: polyethylene glycol 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g.

RX only

Manufactured by Braintree Laboratories, Inc., Braintree, MA 02185

Marketed by Braintree, A part of Sebela Pharmaceuticals®



FILL TO THE TOP OF THE LINE ON BOTTLE

TO PHARMACIST AND PATIENT:

NDC 52268-100-01

Mixing information is on base label.

Package insert may be removed before dispensing.

Dispense the enclosed Medication Guide to each patient.

GoLYTELY®

PEG-3350 and Electrolytes for Oral Solution

When reconstituted with water to a volume of 4 liters, this solution contains PEG-3350 59 g/L, sodium sulfate 5.69 g/L, sodium bicarbonate 1.69 g/L, sodium chloride 1.47 g/L, and potassium chloride 0.743 g/L.

Each disposable jug contains, in powdered form: polyethylene glycol 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g.

R_x only

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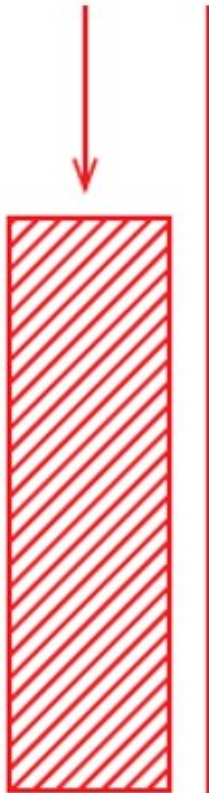
PULL DOWN TO OPEN



Manufactured by Braintree Laboratories, Inc., Braintree, MA 02185

Marketed by

 **Braintree**
A PART OF SEBELA PHARMACEUTICALS®



FILL TO THE TOP OF THE LINE ON BOTTLE

Instructions for Use GoLYTELY® (Go-lite-ly) (PEG-3350 and Electrolytes) for oral solution

Read this Instructions for Use and the Medication Guide before you start taking GoLYTELY.

Important information

- Do not take undissolved GoLYTELY powder that has not been mixed with water (diluted). It may increase your risk of nausea, vomiting and fluid loss (dehydration).
- Do not eat solid foods at least 2 hours before taking GoLYTELY. For best results, do not consume solid food for 3 to 4 hours before drinking GoLYTELY.

Prepare and take GoLYTELY

1. Add lukewarm drinking water to the fill mark (4 liters) on the jug. Do not add any other ingredients or flavors. Do not mix GoLYTELY with starch-based thickeners.
2. Place the cap securely on the jug. Shake the jug very well (vigorously) several times to make sure that the ingredients are mixed well (dissolved).
3. Drink one 8-ounce (240 mL) cup of the mixed solution rapidly every 10 minutes. A loose watery bowel (stool) movement should result in approximately 1 hour. Continue drinking until you finish the entire contents (4-liters), your stools are clear, or as directed by your healthcare provider. If giving GoLYTELY through the nasogastric (NG) tube, place GoLYTELY into the NG tube at a rate of 20 to 30 ml per minute (1.2 or 1.8 liters per hour).
4. Throw away (discard) unused GoLYTELY solution within 48 hours (2 days).

Keep GoLYTELY and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. 05/2021

A 05/21

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NDC 52268-101-01

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Pineapple Flavor

GoLYTELY®

PEG-3350 and Electrolytes for Oral Solution

When reconstituted with water to a volume of 4 liters, this solution contains 125 mmol/L sodium, 10 mmol/L potassium, 40 mmol/L sulfate, 20 mmol/L bicarbonate, 35 mmol/L chloride and 17.6 mmol/L polyethylene glycol 3350.

Each disposable jug contains, in powdered form: polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g, flavor ingredients 3.0 g.

RX only M 9/13

Braintree

Laboratories, Inc

Braintree, MA 02185



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TO PHARMACIST AND PATIENT:
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dispensing.

NDC 52268-101-01

**Dispense the enclosed
Medication Guide to each patient.**

**PINEAPPLE FLAVOR
GoLYTELY®**



PEG-3350 and Electrolytes for Oral Solution

PULL DOWN TO OPEN ↓

When reconstituted with water to a volume of 4 liters, this solution contains 125 mmol/L sodium, 10 mmol/L potassium, 40 mmol/L sulfate, 20 mmol/L bicarbonate, 35 mmol/L chloride and 17.6 mmol/L polyethylene glycol 3350.

Each disposable jug contains, in powdered form:
polyethylene glycol 3350 236 g, sodium sulfate (anhydrous) 22.74 g, sodium bicarbonate 6.74 g, sodium chloride 5.86 g, potassium chloride 2.97 g, flavor ingredients 3.0 g.

Rx only

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LABORATORIES • INC
Braintree Braintree, MA 02185

NDC 52268-700-01
Rx only

**GoLYTELY®
PEG-3350 AND ELECTROLYTES**

FOR ORAL SOLUTION
1 Gallon (3.785 Liters)

Instructions

A GoLYTELY® solution is made up by dissolving the contents of this packet in one gallon of tap water according to the following procedure:

Obtain a food-grade clear container with a volume of at least one gallon.
After cutting open the packet, pour the entire contents into the container.
Add lukewarm drinking water to bring the volume of the solution to one gallon.
Do not add any other ingredients, flavors, etc.

Shake and/or mix thoroughly to ensure that the ingredients are dissolved.
The solution is more palatable if chilled in the refrigerator before drinking. Keep reconstituted solution refrigerated. Use within 48 hours. Discard unused portion.
For best results, no solid food should be consumed for the 3 to 4 hour period before drinking the solution; but in no case should solid food be eaten within two hours of taking GoLYTELY.

Drink one 8 oz. glassful of the solution rapidly every 10 minutes. A loose watery bowel movement should result in approximately one hour. Continue drinking until the rectal effluent is clear or the entire contents (1 gallon) have been consumed or as directed by your physician.

Usual dosage: 1 gallon (3.785 liters).

This package contains:

Polyethylene glycol 3350.....227.1 grams
Sodium sulfate, anhydrous....21.5 grams
Sodium bicarbonate.....6.36 grams
Sodium chloride.....5.53 grams
Potassium chloride.....2.82 grams

APPROXIMATE NET WEIGHT: 263 grams

Distributed by Braintree Laboratories, Inc., Braintree, MA 02185



Dispense the enclosed Medication Guide to each patient

NDC 52268-700-01

R_x only

GoLYTELY[®]

PEG-3350 AND ELECTROLYTES FOR ORAL SOLUTION

1 Gallon (3.785 Liters)

INSTRUCTIONS

A GoLYTELY[®] solution is made up by dissolving the contents of this packet in one gallon of tap water according to the following procedure:

1. Obtain a food-grade clear container with a volume of at least one gallon.
2. After cutting open the packet, pour the entire contents into the container.
3. Add lukewarm drinking water to bring the volume of the solution to one gallon.
4. Do not add any other ingredients, flavors, etc.
5. Shake and/or mix thoroughly to ensure that the ingredients are dissolved.
6. The solution is more palatable if chilled in the refrigerator before drinking. Keep reconstituted solution refrigerated. Use within 48 hours. Discard unused portion.
7. For best results, no solid food should be consumed for the 3 to 4 hour period before drinking the solution; but in no case should solid food be eaten within two hours of taking GoLYTELY.
8. Drink one 8 oz. glassful of the solution rapidly every 10 minutes. A loose watery bowel movement should result in approximately one hour. Continue drinking until the rectal effluent is clear or the entire contents (1 gallon) have been consumed or as directed by your physician.

REV 09/2012

Usual dosage: 1 gallon (3.785 liters).

This package contains:

Polyethylene glycol 3350.	227.1 grams
Sodium sulfate, anhydrous.	21.5 grams
Sodium bicarbonate.	6.36 grams
Sodium chloride.	5.53 grams
Potassium chloride.	2.82 grams



APPROXIMATE NET WEIGHT: 263 grams

Distributed by Braintree Laboratories, Inc., Braintree, MA 02185

GOLYTELY

polyethylene glycol 3350, sodium sulfate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52268-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	236 g in 4 L
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM CATION - UNII:LYR4M0NH37, SULFATE ION - UNII:7IS9N8KPMG)	SODIUM SULFATE ANHYDROUS	22.74 g in 4 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	6.74 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	5.86 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	2.97 g in 4 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52268-100-01	4 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019011	07/13/1984	

GOLYTELY

polyethylene glycol 3350, sodium sulfate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52268-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	236 g in 4 L
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM CATION - UNII:LYR4M0NH37, SULFATE ION - UNII:7IS9N8KPMG)	SODIUM SULFATE ANHYDROUS	22.74 g in 4 L

SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	6.74 g in 4 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	5.86 g in 4 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	2.97 g in 4 L

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PINEAPPLE (PINEAPPLE)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52268-101-01	4 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/13/1984	10/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019011	07/13/1984	10/31/2022

GOLYTELY

polyethylene glycol 3350, sodium sulfate anhydrous, sodium bicarbonate, sodium chloride, potassium chloride powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52268-700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	227.1 g in 1 L
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM CATION - UNII:LYR4M0NH37, SULFATE ION - UNII:7IS9N8KPMG)	SODIUM SULFATE ANHYDROUS	21.5 g in 1 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37, BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	6.36 g in 1 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	5.53 g in 1 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.754 g in 1 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52268-700-01	4 L in 1 PACKET; Type 0: Not a Combination Product	07/13/1984	05/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019011	07/13/1984	05/31/2022

Labeler - Braintree Laboratories, Inc. (107904591)

Establishment

Name	Address	ID/FEI	Business Operations
Braintree Laboratories, Inc.		617357954	manufacture(52268-100, 52268-101, 52268-700)

Revised: 5/2021

Braintree Laboratories, Inc.